Initial Approval: November 14, 2014
Revised Date: January 14, 2015

CRITERIA FOR PRIOR AUTHORIZATION

Fixed Combination Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Ledipasvir/Sofosbuvir (Harvoni®)

CRITERIA FOR INITIAL APPROVAL OF LEDIPASVIR/SOFOSBUVIR: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 24 weeks of Sofosbuvir/Ledipasvir therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 hepatitis C
- Patient must not have a co-infection with HIV
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m^2) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not be taking concurrently with another direct acting hepatitis C agent (i.e. concurrent therapy with Incivek®, Victrelis®, Olysio®, Viekira™ or Sovaldi®)
- Patient must not have been on a previous course of therapy with Sovaldi or Viekira
- If patient was on a previous course of treatment with Incivek, Victrelis or Olysio it must have included an interferon-based regimen
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 capsule per day
- Patient must have one of the following:
- Patient must have one of the following:
    - Advanced fibrosis (Metavir F3)
    - Compensated cirrhosis
    - Liver transplant
    - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg, vasculitis)
    - Proteinuria
    - Nephrotic syndrome
    - Membranoproliferative glomerulonephritis

RENEWAL CRITERIA FOR LEDIPASVIR/SOFOSBUVIR:

- Prescriber must document adherence by patient of greater than or equal to 90% and meet one of the following:
    - Treatment-naïve, without cirrhosis, and a pre-treatment HCV RNA < 6 million IU/mL – **8 weeks total therapy**
    - Treatment-naïve, with or without cirrhosis, and a pre-treatment HCV RNA ≥ 6 million IU/mL – **12 weeks total therapy**
    - Treatment-naïve, with cirrhosis– **12 weeks total therapy**
    - Treatment-experienced, without cirrhosis – **12 weeks total therapy**
    - Treatment-experienced, with cirrhosis – **24 weeks total therapy**

LENGTH OF APPROVAL FOR LEDIPASVIR/SOFOSBUVIR: 4 weeks